REMARKS

Claims 88-206 are pending in the present application. In order to expedite the prosecution of the present application, without acquiescing to the Examiner's rejection, while reserving the right to prosecute the original claims in the future, Applicants have amended Claims 88, 103, 118, 119, 146, 147, 177, and 206. As such, Claims 88-206 are currently pending.

Applicants note that the priority claim has been amended. As amended, the earliest priority date of March 2, 2001 is now derived from U.S. patent application serial number 09/798,007.

Applicants provide herewith the following interview summary to be made of record with respect to the subject application. Applicants thank the Examiner for the helpful interview (hereinafter, "Interview"). The substance of the Interview was as follows:

Participants: David C. Thomas (Examiner), Christopher Sappenfield (Attorney), Jason Ferrone (Attorney), Lisa Mueller (Attorney), and David Ecker (Inventor)
Date of Interview: May 21, 2008
Interview type: Personal
Exhibit shown or demonstration conducted: None
Claims discussed: Independent claims 88, 119, 147, and 178.
Art discussed: The art of record.
Agreement with respect to the claims discussed: Examiner agreed that Declaratory evidence is likely applicable for claims that recite amplification of two or more segments for analysis that employs determination of base compositions without sequencing.
Identification of principal proposed amendments of a substantive nature discussed: None
General indication of any other pertinent matters discussed: Not applicable

General results or outcome of the Interview: Examiner agreed to consider the prior claims (as opposed to the currently amended claims) and the evidence in preparing the present Office Action.

I. Double Patenting

The Office Action rejects claims 27-29, 31-35, 37, 38, 50-60, 62-71, 73-78 and 80-87 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-29 of U.S. Patent No. 7,108,974, claims 1-11 of U.S. Patent No. 7,226,739, claims 1-28 of U.S. Patent No. 7,255,992, and claims 23-27, 30-34, and 44-55 of copending Application No. 10/660,122. Applicants note that the rejected claims were cancelled in the prior filed amendment, rending these rejections moot.

II. The Claims are Definite

The Examiner has rejected Claims 88, 119, and 147 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. The Examiner alleges the claims are not clear in reciting "determining two or more base compositions of said two or more amplification products." In order to expedite the prosecution of the present application, without acquiescing to the Examiner's rejection, while reserving the right to prosecute the original claims in the future, Applicants have amended the claims to recite "determining ~~two or more~~ said base compositions of said two or more amplification products." As such, Applicants respectfully request the rejection be withdrawn.

The Examiner has rejected Claim 103 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. The Examiner alleges the claim is not clear in reciting "two or more different etiologic are selected." In order to expedite the prosecution of the present application, without acquiescing to the Examiner's rejection, while reserving the right to prosecute the original claims in the future, Applicants have amended claims to recite "two or more different etiologic agents are selected." As such, Applicants respectfully request the rejection be withdrawn.

The Examiner has rejected Claims 118, 146, 177, and 206 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. The Examiner alleges the claims are not clear in reciting "two or more segments of nucleic acid are from two or genes selected from." In order to expedite the prosecution of the present application, without acquiescing to the Examiner's rejection, while reserving the right to prosecute the original claims in the future, Applicants have amended Claims to recite "two or more segments of nucleic acid are from two or more genes selected from." As such, Applicants respectfully request the rejection be withdrawn.

III. The Claims are Not Anticipated

The Examiner has rejected Claims 88, 90, 91, 94-98, 100-105, 118, 119, 121, 126-133, 146, 147, 149, 157-164, 177, 180, 186-193, and 206 under 35 U.S.C. 102 as allegedly being anticipated by Lott et al. (Yeast (1993) 9:1199-1206., hereafter referred to as Lott). Applicants respectfully disagree. The Examiner alleges Lott teaches a method of identifying one or more etiologic agents of disease or bioagents in a sample comprising the steps of: amplifying two or more segments of a nucleic acid from said one or more etiologic agents in said sample with two or more primer pairs to obtain two or more amplification products; determining two or more base compositions of said two or more amplification products; and comparing said two or more base compositions with known base compositions of known etiologic agents produced with said two or more primer pairs to identify said one or more etiologic agents in said sample.

In order to expedite the prosecution of the present application, without acquiescing to the Examiner's rejection, while reserving the right to prosecute the original claims in the future, Applicants have amended Claims 88, 119, and 147 to recite the element of "identifying" said one or more etiologic agents (or bioagents) in said sample.

Lott does not teach identifying one or more etiologic agents in a sample. Instead, Lott describes determining the nucleotide sequence for DNA encoding the 5.8S rRNA of *Candida albicans* and several other related species. The identity of the subject taught by Lott is known, and there is no need to provide a method for determining its identity.

There is no teaching that the sequence analysis methods of Lott could or should be used to identify one or more etiologic agents in a sample.

Moreover, Lott does not teach "identifying said one or more etiologic agents in said sample by comparing said base compositions with known base compositions of known etiologic agents." The method of sequencing taught by Lott provides the linear sequences of the analyzed DNA segment. In the presently claimed invention, base composition is defined as identifying the number of A residues, C residues, T residues, G residues, U residues, analogues thereof and mass tag residues thereof. There is no teaching in Lott that the identity of an etiologic agent or bioagent could or should be determined using base composition data. Lott teaches the use of sequence alignments to compare the sequences of the known species of yeast analyzed, which does not and would not utilize base composition analysis for any purpose, let alone identity determination of an organism (which, as discussed above, is not an activity that Lott contemplates).

Based on the Above, applicants respectfully request the rejection for Claims 88, 119, 147, and dependent claims 90, 91, 94-98, 100-105, 118, 121, 126-133, 146, 149, 157-164, 177, 180, 186-193, and 206 be withdrawn.

The Examiner has further rejected Claims 88, 89, 92-94, 106, 107, 110, 119, 120, 122-124, 129, 133, 138, 147, 148, 150, 153-155, 160, 165, 166, 169, 178, 179, 181, 184, 189, 194, 195, and 198 under 35 U.S.C. 102 as allegedly being anticipated by Hurst et al. (Rapid Comm. Mass Spectrom. (1996) 10:377-382, hereafter referred to as Hurst). Applicants respectfully disagree. The Examiner alleges that Hurst teaches a method of identifying one or more etiologic agents or bioagents in a sample, comprising the steps of: amplifying two or more segments of a nucleic acid from said one or more etiologic agents in said sample with two or more primer pairs to obtain two or more amplification products; determining two or more base compositions of said two or more amplification products via mass spectrometry, without sequencing; and comparing said two or more base compositions with known base compositions of known etiologic agents produced

with said two or more primer pairs to identify said one or more etiologic agents in said sample.

In order to expedite the prosecution of the present application, without acquiescing to the Examiner's rejection, while reserving the right to prosecute the original claims in the future, Applicants have amended Claims 88, 119, and 147 to recite "determining said base compositions of said two or more amplification products, wherein said base compositions identifies the number of A residues, C residues, T residues, G residues, U residues, analogues thereof and mass tag residues thereof." Hurst does not teach a method for determining the base composition of the amplified segments. Hurst describes using MALDI-TOF to determine the mass of a PCR amplified DNA segment, in order to estimate the length of the DNA segment (e.g. 108 DNA bases or 168 DNA bases). Hurst does not describe or suggest a method of determining "the number of A residues, C residues, T residues, G residues, U residues, analogues thereof and mass tag residues thereof" as provided by the presently claimed invention. The reference does not teach each element of the claimed invention. Likewise, with respect to claim 178, Hurst does not teach or suggest determining the mass of "two or more" amplification products and comparing these masses to "a database containing known masses of known bioagents" "to identify" the bioagent. Hurst does not use a database of known masses to assess two or more amplification products to identify the bioagent. There is no basis in Hurst for using a database. As such, Applicants respectfully request the rejection for Claims 88, 119, 147, and dependent claims 89, 92-94, 106, 107, 110, 120, 122-124, 129, 133, 138, 148, 150, 153-155, 160, 165, 166, 169, 178, 179, 181, 184, 189, 194, 195, and 198 be withdrawn.

IV. The Claims are Not Obvious

The Examiner has rejected Claims 99, 108, 109, 111-117, 125, 136, 137, 139-145, 151, 147, 152, 156, 167, 168, 170-176, 182, 183, 185, 196, 197, and 199-205 under 35 U.S.C. 103(a) as allegedly being obvious over Hurst in view of Koster et al. (WO 98/20166; hereafter referred to as Koster). Applicants respectfully disagree. It is noted that this rejection is directed at certain dependent claims and applies Koster to Hurst with

the understanding that Hurst anticipates the independent claims, but lacks elements of the dependent claims. In the rejection, Koster is added to Hurst to argue that these dependent claims, that are otherwise free of Hurst, are obvious.

As Applicants note above, in view of the presently amended claims, Hurst lacks elements of the independent claims. Koster does not remedy these deficiencies of Hurst. For example, Koster, like Hurst, does not teach or suggest "determining said base compositions of said two or more amplification products, wherein said base compositions identifies the number of A residues, C residues, T residues, G residues, U residues, analogues thereof and mass tag residues thereof." There is a use of the term "base composition" in the Koster reference (page 105 and in Table 2), but this term is used in a different context and does not teach of suggest use of base composition analysis for identifying biological agents. Likewise, Koster does not teach or suggest a database of amplicon masses that is analyzed to assess two or more different amplicons to identify a bioagent.

Further, the rejection acknowledges that Hurst does not teach a method wherein bacteria are from two different subspecies or are from two different genera selected from the group listed above. The rejection further acknowledges that Hurst does not teach a method wherein one or more etiologic agents or bioagents comprise at least one bacterium and at least one virus, two different viruses from two different species or subspecies, an unknown etiologic agent, or two different viruses from two different viral families. The teachings of Koster do not overcome this deficit. Koster teaches that the disclosed process can be used for the detection of a list of both bacteria and viruses; however, Koster does not teach a method wherein: bacteria are from two different subspecies, bacteria are from two different genera, at least one bacterium and at least one virus, two different viruses from two different species, an unknown etiologic agent, or two different viruses from two different viral families. As such neither reference teaches all the elements of claims 108, 109, 111-117, 136, 137, 139-145, 167, 168, and 170-176.

Lastly, Applicants previously submitted a Declaration of Buchsbaum that provides evidence of non-obviousness, showing scepticism in the field. This Declaration was previously dismissed by the Examiner as not pertaining to the claims because the

claims pending at the time did not, according to the Examiner, have sufficient nexus to the scepticism described in the Declaration. In particular, the claims pending at that time, according to the Examiner, did not recite the use of primers to generate multiple different amplification products that could be used to identify a bioagent or bioagents by comparing base compositions to known bioagent base compositions. The present claims do provide this nexus and Applicants request that the Declaration, which was not addressed in the current Office Action, be considered. It is noted that in the Examiner's interview summary of November 6, 2008, the Examiner stated that, "The Declaration of Buchsbaum will likely be applicable if the claims cite amplification of two or more segments for analysis by the methods that measure base composition without sequencing."

Based on the above, Applicants submit that the references of Hurst and Koster do not render the presently claimed invention obvious. As such, applicants respectfully request the rejection for Claims 99, 108, 109, 111-117, 125, 136, 137, 139-145, 151, 147, 152, 156, 167, 168, 170-176, 182, 183, 185, 196, 197, and 199-205 be withdrawn.

CONCLUSION

All grounds of rejection of the Office Action have been addressed, and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicants' claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: May 4, 2009

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